(2) Detailed information concerning the qualified handler's name, address, and telephone and fax numbers;

(3) The month(s) for which the request is made;

(4) Total assessments due;

(5) The percent of the outstanding debt to be paid each month after the postponement of payment is granted; and

(6) The starting date for the payment of assessments due.

(b) At the end of the postponement period, the qualified handler must pay the percentage of assessments due specified per month and the current month assessment due. If an extension of time is requested, new documentation must be provided for the Council to determine whether to grant the extension. The same procedures used for the initial request will be used to grant any extension.

Dated: November 20, 1995.

Robert C. Kenny,

Director, Fruit and Vegetable Division.

[FR Doc. 95–28770 Filed 11–24–95; 8:45 am]

BILLING CODE 3410–02–P

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. 93–128–1]

Viruses, Serums, Toxins, and Analogous Products; Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Standard Requirement for Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, by specifying requirements for killed Venezuelan equine encephalomyelitis vaccines and revising the standard potency test for eastern and western encephalomyelitis vaccines. The effect of the proposed amendment would be to require the use of Vero 76 cells in the test to evaluate the potency of Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus, and to establish minimum antibody titers which must be elicited by each of the indicated fractions, as determined by a plaque reduction, serum neutralization assay in which Vero 76 cells are used.

DATES: Consideration will be given only to comments received on or before January 26, 1996.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 93–128–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 93–128–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m. Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead (202)-690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. David Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1237, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the regulations contained in 9 CFR part 113, standard requirements are prescribed for the preparation of veterinary biological products. A standard requirement consists of test methods, procedures, and criteria established by the Animal and Plant Health Inspection Service to help ensure that veterinary biological products are pure, safe, potent, and efficacious.

The standard requirement for Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, in § 113.207, specifies minimum potency requirements for such products. A serial of Eastern and Western equine encephalomyelitis vaccine must induce at least minimum antibody titers in guinea pigs specific for each fraction. The current standard requirement states that titers are to be determined in a plaque reduction, serum neutralization test but does not specify the cell type to be employed in the test. Primary duck embryo fibroblasts (DEF) were once considered the cells of choice; however, difficulties in producing acceptable DEF cultures are often encountered and results obtained with such cultures are not always consistent. These problems are not seen with cells of the Vero (African green monkey kidney) 76 cell line.

This proposed rule would revise the standard requirement in § 113.207 to require that cells of the Vero 76 cell line be used in encephalomyelitis vaccine potency tests. It would also revise the standard requirement by changing the minimum specific antibody titers from 1:4 to 1:40 for Eastern equine encephalomyelitis virus (EEV) and 1:32 to 1:40 for Western EEV. Extensive correlation work performed by the National Veterinary Services Laboratories (NVSL) indicates these new minimum specific antibody titers as measured using Vero 76 cells are equivalent to those currently specified in the standard requirement as measured with DEF.

In addition, the proposed rule would revise the standard requirement to establish standard test requirements for Encephalomyelitis Vaccine, Venezuelan, Killed Virus, and set 1:4 as the minimum specific antibody titer such vaccines must obtain to pass the potency test. The Agency has determined that a product that induces an anti-Venezuelan equine encephalomyelitis virus titer (as measured using Vero 76 cells) in guinea pigs of 1:4 or greater should protect horses against disease caused by that virus.

This proposed rule would establish uniform test requirements for all killed vaccines for the prevention of Venezuelan equine encephalomyelitis and would revise the current potency test to make it more reliable and consistent. Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for purposes of Executive Order 12866, and, therefore, has not been reviewed by the Office of Management and Budget.

This proposed rule would revise the standard requirement in § 113.207 for Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, by specifying a different cell type for use in the potency test assay and specifying different minimum specific antibody titers that must be achieved for a satisfactory test. In addition, the proposed rule would revise the standard requirement so that it would also apply to Encephalomyelitis Vaccine, Venezuelan, Killed Virus. The Agency believes the titers given in the standard requirement are adequately correlated with claimed efficacy and that they would be readily obtained by all relevant vaccines currently licensed. We do not expect any increase in cost to the biologics manufacturers affected by this proposed rule. The changes should actually decrease costs for most impacted manufacturers, since fewer repeat tests will be needed and obtaining Vero 76 cells should prove less expensive than procuring primary DEF.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not

have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.).

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

List of Subjects in 9 CFR Part 113

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 113 would be amended as follows:

PART 113—STANDARD REQUIREMENTS

1. The authority citation for part 113 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

2. In § 113.207, the section heading, the introductory text, the introductory text of paragraph (b), and paragraphs (b)(2), (b)(3), (b)(4), and (b)(5) would be revised to read as follows:

§ 113.207 Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus.

Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Each serial or subserial shall meet the requirements prescribed in this section and the general requirements prescribed in § 113.200, except those in § 113.200(d). Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

* * * * *

(b) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested for potency in accordance with the two-stage test provided in this paragraph. For each fraction contained in the product—Eastern type, Western type, or Venezuelan type—the serological interpretations required in this test shall be made independently. A serial or subserial found unsatisfactory for any of the fractions shall not be released.

(1) * * *

(2) Fourteen to 21 days after the second injection, serum samples from each vaccinate and each control shall be tested by a plaque reduction, serum neutralization test using Vero 76 cells.

(3) If the control serum samples show a titer of 1:4 or greater for any fraction, the test is inconclusive for that fraction and may be repeated: *Provided,* That, if four or more of the vaccinate serum samples show a titer of less than 1:40 for the Eastern type fraction, less than 1:40 for the Western type fraction, or less than 1:4 for the Venezuelan type fraction, the serial or subserial is unsatisfactory without further testing.

(4) If two or three of the vaccinate serum samples show a titer of less than 1:40 for the Eastern type fraction, less than 1:40 for the Western type fraction, or less than 1:4 for the Venezuelan type fraction, the second stage of the test may be used for the relevant fraction(s): *Provided,* That, if a fraction is found acceptable by the first stage of the test, the second stage need not be conducted for that fraction.

(5) If the second stage is used and four or more of the vaccinate serum samples show a titer of less than 1:40 for the Eastern type fraction or the Western type fraction, or less than 1:4 for the Venezuelan type fraction, the serial or subserial is unsatisfactory.

* * * * *

Done in Washington, DC, this 20th day of November 1996.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–28764 Filed 11–24–95; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[Docket No. PRM–50–63]

Peter G. Crane, Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking filed by Mr. Peter G. Crane. The petition has been docketed by the Commission and has been assigned Docket No. PRM–50–63. The petitioner requests that the NRC amend its regulations concerning emergency planning to include a requirement that emergency planning protective actions include sheltering, evacuation, and the prophylactic use of potassium iodide, which prevents thyroid cancer after nuclear accidents. The request would amend one of the 16 planning standards in 10 CFR 50.47 by which licensee emergency plans are evaluated in order to assure that the option of using potassium iodide is included in emergency planning.

DATES: Submit comments by February 12, 1996. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except to those comments received on or before this date.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Attention: Docketing and Services Branch.

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm on Federal workdays.

For a copy of the petition, write: Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. For information on submitting comments electronically, see ''Electronic Access'' under Supplementary Information.

FOR FURTHER INFORMATION CONTACT: Michael Jamgochian, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301–415–6534, or Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301–415–7163 or Toll Free: 800–368–5642.

SUPPLEMENTARY INFORMATION:

Electronic Access

Comments may be submitted electronically, in either ASCII text or WordPerfect format (version 5.1 or later), by calling the NRC Electronic Bulletin Board (BBS) on FedWorld. The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or